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109TH CONGRESS
1ST SESSION

H. R. 1822

To prohibit human cloning and protect stem cell research.

IN THE HOUSE OF REPRESENTATIVES

APRIL 26, 2005

Mrs. BONO (for herself, Ms. DEGETTE, Mr. CASTLE, Mr. MARKEY, and Mr. BASS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To prohibit human cloning and protect stem cell research.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Human Cloning Ban and Stem Cell Research Protection Act of 2005''.

SEC. 2. PURPOSES.

It is the purpose of this Act to prohibit human cloning and to protect important areas of medical research, including stem cell research.

TITLE I—PROHIBITION ON HUMAN CLONING

SEC. 101. PROHIBITION ON HUMAN CLONING.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by adding at the end the following:

"CHAPTER X—PROHIBITION ON HUMAN CLONING

"SEC. 1001. PROHIBITION ON HUMAN CLONING.

''(a) DEFINITIONS.—In this section:

''(1) HUMAN CLONING.—The term 'human cloning' means implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus.

''(2) HUMAN SOMATIC CELL.—The term 'human somatic cell' means any human cell other than a haploid germ cell.

''(3) NUCLEAR TRANSPLANTATION.—The term 'nuclear transplantation' means transferring the nucleus of a human somatic cell into an oocyte from which the nucleus or all chromosomes have been or will be removed or rendered inert.

''(4) NUCLEUS.—The term 'nucleus' means the cell structure that houses the chromosomes.

''(5) OOCYTE.—The term 'oocyte' means the female germ cell, the egg.

''(6) UNFERTILIZED BLASTOCYST.—The term 'unfertilized blastocyst' means an intact cellular structure that is the product of nuclear transplantation. Such term shall not be construed to include any biological product derived from an intact cellular structure that is the product of nuclear transplantation, including stem cells, other cells, and cellular structures.

''(b) PROHIBITIONS ON HUMAN CLONING.—It shall be unlawful for any person or other legal entity, public or private—

''(1) to conduct or attempt to conduct human cloning;

''(2) to ship the product of nuclear transplantation in interstate or foreign commerce for the purpose of human cloning in the United States or elsewhere; or

''(3) to export to a foreign country an unfertilized blastocyst if such country does not prohibit human cloning.

''(c) PROTECTION OF RESEARCH.—Nothing in this section shall be construed to restrict practices not expressly prohibited in this section.

''(d) RIGHT OF ACTION.—Nothing in this section shall be construed to give any individual or person a private right of action.''.

(b) PROHIBITED ACTS.—

(1) IN GENERAL.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh) The violation of paragraph (1), (2), or (3) of section 1001(b) (relating to human cloning).''.

(2) CRIMINAL PENALTIES.—Section 303(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(b)) is amended by adding at the end the following:

''(7) Notwithstanding subsection (a), any person who violates section 301(hh) shall be imprisoned not more than 10 years and fined in accordance with title 18, United States Code, or both.''.

(3) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end:

''(g)(1) Any person who violates section 301(hh) shall be liable to the United States for a civil penalty in an amount not to exceed the greater of—

''(A) $10,000,000; or

''(B) an amount equal to three times the amount of the gross pecuniary gain resulting from the violation.

''(2) Paragraphs (3) through (5) of subsection (f) apply with respect to a civil penalty under this subsection to the same extent and in the same manner as such paragraphs (3) through (5) apply with respect to a civil penalty under subsection (f).''.

(4) FORFEITURE.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as amended by paragraph (3), is amended by adding at the end the following:

''(h) Any property, real or personal, derived from or used to commit a violation or attempted violation of section 301(hh), or any property traceable to such property, shall be subject to forfeiture to the United States in accordance with the procedures set forth in chapter 46 of title 18, United States Code.''.

SEC. 102. OVERSIGHT REPORTS ON ACTIONS TO ENFORCE CERTAIN PROHIBITIONS.

(a) REPORT ON ACTIONS BY SECRETARY OF HHS TO ENFORCE PROHIBITION ON HUMAN CLONING.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on the Judiciary of

the Senate and the Committee on Energy and Commerce of the House of Representatives a report that—

(1) describes the actions taken by the Secretary to enforce the provisions of chapter X of the Federal Food, Drug, and Cosmetic Act (as added by section 101);

(2) describes the personnel and resources the Secretary has utilized to enforce the provisions of such chapter; and

(3) contains a list of violations, if any, of the provisions of such chapter.

(b) REPORT ON COORDINATION OF ENFORCEMENT ACTIONS AMONG FEDERAL, STATE, AND LOCAL GOVERNMENTS WITH RESPECT TO HUMAN CLONING.—

(1) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on the Judiciary of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that—

(A) describes how the Secretary coordinates the enforcement of violations of section 301(hh) of the Federal Food, Drug, and Cosmetic Act (as added by section 101) with enforcement actions taken by State or local gov-

ernment law enforcement officials with respect to similar State laws relating to human cloning; and

(B) describes the status and disposition of—

(i) Federal appellate litigation with respect to such section 301(hh) and State appellate litigation with respect to similar State laws relating to human cloning; and

(ii) civil litigation, including actions to appoint guardians, related to human cloning.

(2) DEFINITION.—In this subsection, the term ''similar State law relating to human cloning'' means a State or local law that provides for the imposition of criminal penalties on individuals who are determined to be conducting or attempting to conduct human cloning (as defined in section 1001 of the Federal Food, Drug, and Cosmetic Act (as added by section 101)).

(c) REPORT ON INTERNATIONAL LAWS RELATING TO HUMAN CLONING.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Congress a report that—

(1) describes the laws adopted by foreign countries related to human cloning;

(2) describes the actions taken by the chief law enforcement officer in each foreign country that has enacted a law described in paragraph (1) to enforce such law; and

(3) describes the multilateral efforts of the United Nations and elsewhere to ban human cloning.

TITLE II—ETHICAL REQUIREMENTS FOR NUCLEAR TRANSPLANTATION RESEARCH

SEC. 201. ETHICAL REQUIREMENTS FOR NUCLEAR TRANSPLANTATION RESEARCH.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

"PART J—ETHICAL REQUIREMENTS FOR NUCLEAR TRANSPLANTATION RESEARCH

"SEC. 499A. ETHICAL REQUIREMENTS FOR NUCLEAR TRANSPLANTATION RESEARCH, INCLUDING INFORMED CONSENT, INSTITUTIONAL REVIEW BOARD REVIEW, AND PROTECTION FOR SAFETY AND PRIVACY.

''(a) DEFINITIONS.—

''(1) IN GENERAL.—The definitions contained in section 1001(a) of the Federal Food, Drug, and Cosmetic Act shall apply for purposes of this section.

''(2) OTHER DEFINITIONS.—In this section:

''(A) DONATING.—The term 'donating' means giving without receiving valuable consideration.

''(B) FERTILIZATION.—The term 'fertilization' means the fusion of an oocyte containing a haploid nucleus with a male gamete (sperm cell).

''(C) VALUABLE CONSIDERATION.—The term 'valuable consideration' does not include reasonable payments—

''(i) associated with the transportation, processing, preservation, or storage of a human oocyte or of the product of nuclear transplantation research; or

''(ii) to compensate a donor of one or more human oocytes for the time or inconvenience associated with such donation.

''(b) APPLICABILITY OF FEDERAL ETHICAL STANDARDS TO NUCLEAR TRANSPLANTATION RESEARCH.—Research involving nuclear transplantation shall be conducted in accordance with subpart A of part 46 of title

45, or parts 50 and 56 of title 21, Code of Federal Regulations (as in effect on the date of the enactment of the Human Cloning Ban and Stem Cell Research Protection Act of 2005), as applicable.

''(c) PROHIBITION ON CONDUCTING NUCLEAR TRANSPLANTATION ON FERTILIZED EGGS.—A somatic cell nucleus shall not be transplanted into a human oocyte that has undergone or will undergo fertilization.

''(d) FOURTEEN-DAY RULE.—An unfertilized blastocyst shall not be maintained more than 14 days from its first cell division, not counting any time during which it is stored at temperatures less than zero degrees centigrade.

''(e) VOLUNTARY DONATION OF OOCYTES.—

''(1) INFORMED CONSENT.—In accordance with subsection (b), an oocyte may not be used in nuclear transplantation research unless such oocyte shall have been donated voluntarily by and with the informed consent of the woman donating the oocyte.

''(2) PROHIBITION ON PURCHASE OR SALE.—No human oocyte or unfertilized blastocyst may be acquired, received, or otherwise transferred for valuable consideration if the transfer affects interstate commerce.

''(f) SEPARATION OF IN VITRO FERTILIZATION LABORATORIES FROM LOCATIONS AT WHICH NUCLEAR TRANSPLANTATION IS CONDUCTED.—Nuclear transplantation may not be conducted in the same laboratory or other physical facility in which human oocytes are subject to assisted reproductive technology treatments or procedures.

''(g) CIVIL PENALTIES.—Whoever intentionally violates any provision of subsections (b) through (f) shall be subject to a civil penalty in an amount that is appropriate for the violation involved, but not more than $250,000.''.

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